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June 29, 2000

Dockets Management Branch (HFA 305)
FDA
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sirs:

Having read some of the news accounts of the Over-The-Counter meeting this week, I would like to submit this additional letter for the FDA's consideration.

In my view, the decision of whether a drug should be OTC or prescription should be solely the FDA's. The issue should be able to be brought to the FDA's attention by a manufacturer or by a person or an organization. The decision should be based on the facts and whether a drug requires a prescriber's skill and knowledge for it to be taken appropriately and safely. This decision should not be influenced by whether a manufacturer desires the drug to be Rx or OTC; it should only be influenced by the facts about the drug.

This was the basis for my letter about inhaled steroids for asthma. I do not know the wishes of any manufacturer of any of these products. I do know that some homeless children living in shelters in New York City are unable to get their medicine because they are unable to arrange for refill prescriptions and that, based on the facts I presented, there should be no need for prescriptions for this class of drugs. For these reasons, I asked the FDA to consider making inhaled steroids and cromolyn OTC. The decision about this should be based on the drug facts, and the appropriate professional opinions and judgements about what is best for patients. The commercial interests of the manufacturers should be irrelevant in this decision-making process.

Sincerely yours,

Marcus Reidenberg

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